August 24, 2018

Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1720-NC
Baltimore MD 21244.8013

Submitted electronically through www.regulations.gov.

Attention: RFI Regarding the Physician Self-Referral Law (CMS-1720-NC)

The NEMT benefit is a key element of a coordinated care plan for Medicaid beneficiaries. An analysis[1] of data from a manager or "broker" of non-emergency medical transportation (NEMT) programs for state Medicaid programs showed that the majority of NEMT services are for regularly scheduled, non-emergency medical trips for individuals requiring additional assistance with transportation to coordinated care for behavioral health services, substance abuse treatment and dialysis services.

Simon&Co. applauds the Administration's efforts to identify regulatory requirements or prohibitions that may act as barriers to coordinated care and alternative payment models. However, Simon&Co. cautions against changes to the self-referral law without taking into account the impact of important conflict of interest protections in the Medicaid statute that reference the physician referral law[2]. Specifically, Simon&Co. is concerned about the Medicaid requirement that, with a few exceptions, brokers of NEMT services not own transportation assets such as cab companies or ambulances.

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[1] Kaiser Commission on Medicaid and the Uninsured. Medicaid Non-Emergency Medical Transportation: Overview and Key Issues in Medicaid Expansion Waivers. February 24, 2016. https://www.kff.org/medicaid/issue-brief/medicaid-non-emergency-medical-transportation-overview-and-key-issues-in-medicaid-expansion-waivers/

[2] State Plans For Medical Assistance, Sec 1902(a)(70)(B)(iv):
(70) at the option of the State and notwithstanding paragraphs (1), (10)(B), and (23), provide for the establishment of a non-emergency medical transportation brokerage program in order to more cost-effectively provide transportation for individuals eligible for medical assistance under the State plan who need access to medical care or services and have no other means of transportation which—
(B) may be conducted under contract with a broker who—
(iv) complies with such requirements related to prohibitions on referrals and conflict of interest as the Secretary shall establish (based on the prohibitions on physician referrals under section 1877 and such other prohibitions and requirements as the Secretary determines to be appropriate);

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Impact of Changes on Medicaid NEMT Broker State Option

The physician self-referral laws were drafted when fee-for-service was the predominant healthcare reimbursement model and changes may be needed as healthcare moves towards value-based purchasing and coordinated care models. However, changes to the self-referral law impacts other parts Medicaid managed care policy such as Medicaid NEMT broker conflict of interest requirements.

The Deficit Reduction Act (Public Law 109-171) that created the Medicaid NEMT broker program specified that states may only contract with an NEMT broker that "complies with such requirements related to prohibitions on referrals and conflict of interest as the Secretary shall establish based on the prohibitions on physician referrals under section 1877 and such other prohibitions and requirements as the Secretary determines to be appropriate." When the DRA was enacted, Congress noted that having a brokerage owned by a company that provides transportation could result in higher costs and a higher potential for fraud or abuse[3].

The regulations[4] implementing the Medicaid NEMT broker option prohibit federal matching payment for the State's expenditures if the contracted manger or an immediate family member has a financial relationship with a transportation provider, with some exceptions[5]. The regulation does this by explicitly substituting "transportation broker" for "physician" and "non-emergency transportation" substituted for "designated health services."

> (A) Except as provided in paragraph (a)(4)(ii)(B) of this section, prohibits the broker (including contractors, owners, investors, Boards of Directors, corporate officers, and employees) from providing non-emergency medical transportation services or making a referral or subcontracting to a transportation service provider if:
>
> (1) The broker has a financial relationship with the transportation provider as defined at § 411.354(a) of this chapter with "transportation broker" substituted for "physician" and "non-emergency transportation" substituted for "DHS";
>
> (2) The broker has an immediate family member, as defined at § 411.351 of this chapter, that has a direct or indirect financial relationship with the transportation provider, with the term "transportation broker" substituted for "physician."

[3] CMS. "Medicaid Program; State Option To Establish Non-Emergency Medical Transportation Program; Final Rule." 73 FR 77519 . 12/19/2008.

[4] 42 CFR § 440.170

[5] The regulation included exceptions to the prohibitions for a non-governmental broker that provided transportation in a rural area (as defined in § 412.62(f)(1)(iii)) when there was no other qualified provider available; when the necessary transportation provided by the non-governmental broker was so specialized that no other qualified provider was available; or when the availability of qualified providers other than the non-governmental broker was insufficient to meet the existing need.

A key tenant of the NEMT broker model is that the transportation service is provided at the most appropriate and lowest cost alternative. The self-referral provision ensures a manager does not refer services to a transportation provider at a higher level of service in which it has a financial interest. For instance, if the broker owns several basic life support-level ambulances, there is a financial incentive to schedule a transport at that level to recoup higher reimbursement for itself or its subsidiary when a van would have been sufficient. As in similar physician cases, it would be difficult for a Medicaid state agency to detect if brokers that also provide transportation could possibly bill for services that did not occur.

Questions from the RFI
Simon&Co. would also like to respond to the following questions in the RFI:

Question 3. *What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an alternative payment model? Specifically, what types of financial arrangements and/or remuneration related to care integration and coordination should be protected and why? How (if at all) should a new exception (or exceptions) protect individual DHS referrals (see 42 CFR 411.355), ownership or investment interests (see 42 CFR 411.356), or compensation arrangements (see 42 CFR 411.357)?*

The OIG Final Rule, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (RIN 0936-AA06) protects free or discounted local transportation of no more than 25 miles made available to established patients (and, if needed, a person to assist the patient) to obtain medically necessary items and services. The organizations offering transportation can use vouchers as well as directly providing the transportation.

HHS intends to issue an RFI on anti-kickback regulations that are obstacles to coordinated care soon. Nonetheless, CMS should clarify that providers offering non-emergency transportation that own the vehicle cannot then submit a Medicaid claim (for Medicaid-eligible beneficiaries) for reimbursement. Despite the protections of the safe harbor currently, filing a Medicaid claim would be a conflict of the self-referral law.

Question 20. *Please share your thoughts regarding whether CMS should measure the effectiveness of the physician self-referral law in preventing unnecessary utilization and other forms of program abuse relative to the cost burden on the regulated industry and, if so, how CMS could estimate this.*

Simon&Co. encourages CMS to measure the effectiveness of the physician self-referral law, particularly as it is applied in managed care such as Medicaid NEMT. In order to estimate this, CMS can examine the reduction in utilization and improvement in right-sizing the transport when a state moves from a NEMT system allowing managers to own the mode of transportation to a brokered system with strict ownership prohibitions.

This was the case in Maine Medicaid NEMT in 2013. The state moved from a system of NEMT manager that used vehicles owned by the manager to one that prohibited self-referred trips using Maine Department of Transportation (MaineDOT) leased vehicles and other vehicles with employees hired by the managers. CMS notified the state that this policy was in conflict with the self-referral prohibitions and the state issued a request for proposals correcting this deficiency. Now, Maine contracts with three independent brokers[6] for regional contracts that adhere to the self-referral prohibitions.

Conclusion

When testifying before the House Ways and Means Health Subcommittee, HHS Deputy Secretary Eric Hagan testified that "We do not want people referred to services they don't need or steered to less convenient, lower quality, or more expensive healthcare providers because of their healthcare provider's financial interest". It is important that the CMS Center for Medicare be cognizant of how the Medicaid NEMT broker regulations are directly impacted by changes in the Medicare self-referral laws and could result in more expensive, lower quality Medicaid transportation.

Simon&Co. asks CMS to be aware of other programs that refer to the Medicare self-referral laws when easing barriers coordinated care. Simon&Co. suggests CMS should clarify that Medicaid providers using an anti-kickback exemption to offer transportation should not then be able to bill Medicaid for the services as this is a self-referral violation. Finally, as a way to quantify the impact of the self-referral prohibitions, Simon&Co. offers the transition in Maine from NEMT managers with interest in offering higher levels of service to managers that focus on the most appropriate and lowest cost alternative.

Simon&Co. appreciates the opportunity to provide CMS with this information. Please contract us if you have any questions.

Sincerely,

Marsha Simon, President

[6] MaineCare Services Non-Emergency Transportation (NET); https://www.maine.gov/dhhs/oms/nemt/nemt_index.html